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STUDY OF MOISTURE CONTENT ELIMINATION IN POLYPROPYLENE BLOOD BAG MANUFACTURING

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ABSTRACT

Nowadays blood bag manufacturing industries are facing a problem in the drying process during the manufacture of blood bags. The drying process is meant to vaporize all the moisture content in the primary packing of the product to make it more sterile. But more than 30% of the blood bags are being rejected by the QA department due to the presence of moisture in the packing even after drying for about 6-8 hours. The presence of water droplets in the packing increases the chance for bacterial and fungal growth. The study was conducted for finding out the main causes for moisture retention in blood bag primary packing. Feasible remedial measures are suggested after analyzing the causes and effects. This will result in better productivity and enhanced quality control in surgical blood bag manufacture.

KEYWORDS: Anti-coagulant, Autoclaving, Condensation, Moisture, Drying Chamber, Root cause analysis.

INTRODUCTION:

Operations involved in the manufacturing process of sterile Blood Bag for pharmaceutical applications are, Plastic processing, Assembly, Pharmacy, Autoclaving and Packing

The confirming product should be transparent and virtually colourless. It should be flexible and sterile, non-pyrogenic and free from toxicity. The product should be non-frangible and clinically compatible. It should be physically, chemically and biologically stable and penetration of micro-organisms must be arrested.

The physical requirements include sterilization, transparency and colourlessness. The temperature withstanding capacity should be at 800 C for 24 hrs with subsequent immersion in water at 500 C for 20 minutes. There should not be more than 2% loss of water content on storage for six weeks. It should be resistant to leakage. The bag should withstand an acceleration of 5000g for 30 min at 4 deg C -37 deg C. The label should be as prescribed.

MATERIALS AND METHODS:

After the manufacturing the bags will be filled with anti-coagulant chemical. Then the bags are kept for sterilization for 6hrs using pure steam for boilers. During this process steam enters the primary packing which is of poly propylene material. As a result of this steam sterilization water droplets will be formed inside the walls of the primary packing. This will cause the growth of microbes and bacterial colonisation inside the packing which will lead to health problems and rejection of blood bags. So to remove the presence of moisture content of packing the blood bags are kept for drying in drying chamber for 10-16 hours.

The main objective of drying is to remove all moisture content in the packing but in some cases even after 16hours the presence of moisture is observed which leads to the rejection of the blood bag and as a result those bags will be kept for re-drying. This appearance of moisture will the smooth product flow and efficiency of the plant.

Data collected from inspection log book rejection due to moisture content was collected in 3 months from the shift log book of the company and is tabulated (Table. 1). The rejections due to moisture content are:

Table 1: Data in 3 months

Month	Total Loaded	Rejected Due to Moisture	Moisture Rejection Percentage
July	321761	110957	34.487
August	266162	83510	31.27
September	388049	137515	35.43

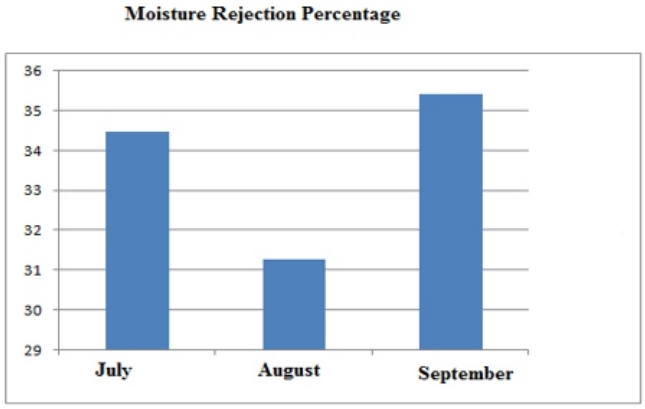

Figure 1: Bar Chart showing rejection of blood bags due to moisture content

Upon observation of all the types of bags after drying, it has been found that the moisture patterns can be classified into 2 types.

1) Moisture in the form of visible water

2) Moisture having a foggy appearance initially, but becoming more visible after curing of bags.

RESULTS:

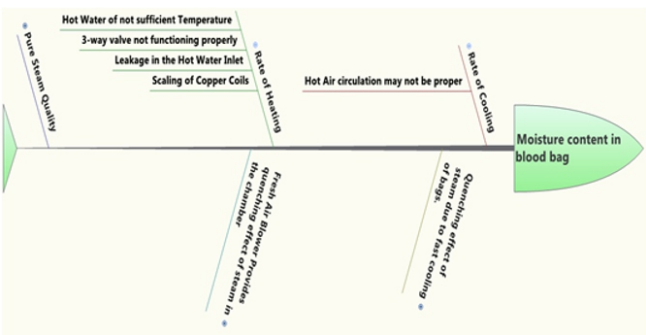

Figure 2: Cause-and-effect diagrams or Ishikawa diagrams (Fish bone diagram)

It was used in the study to identify the major root cause contributing the presence of moisture content in the primary packing of the blood bag.

It is observed that the moisture content on the trays after autoclaving is very high. It is visible as pools of water on the trays.

Possible causes:
Pure steam quality may not be sufficient, thereby increasing the water being sprayed on the bags during sterilization.
A moisture separator has been installed upon supplier's advice, during equipment installation. This may not be functioning efficiently.

RATE OF HEATING:
The rate of heating during the heating cycle of drying is found to be slower than the expected rate. The 4th oven is provided an additional forced exhaust and hence the improved rate of heating and cooling.

Possible causes:
Hot water tank may not be generating Hot water of sufficient temperature

Leakages in the hot water inlet line may be present.

The 3 - way valve on top of each zone of the drying chamber may not be functioning properly. Scaling of copper coils may be inhibiting heat transfer.

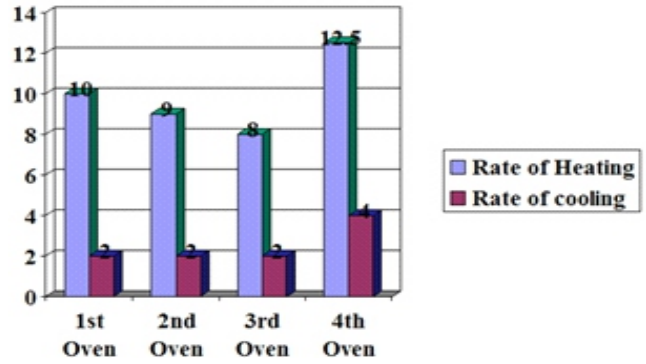

Figure 3: Rate of Heating.

RATE OF COOLING:
The rate of cooling during cooling phase of drying is found to be very slow, when compared against the expected rate.

Possible causes:
Immediately after heater is switched off, the fans at the top (whose primary function is to transfer heat from the hot coils to the rest of the chamber) are still running. As the copper coils will be hot even after heater is switched off, the action of the above-mentioned fans will inhibit cooling.

The air jet from the Bottom fan for fresh air inlet is not reaching the trays at the top. This could be inferred from the fact that the top trays and ceiling of the chamber were found to be hot.

Air Circulation inside the chamber, during cooling, may not be effective enough to get proper drying.

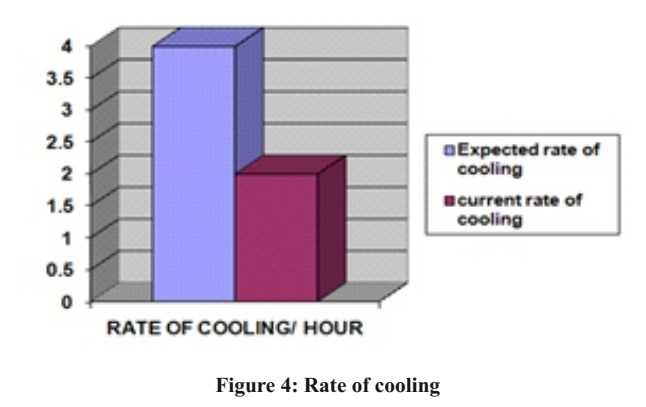

Figure 4: Rate of cooling

DISCUSSION:
From cause and effect diagram, the root causes of presence of moisture content in the primary packing of the blood bag. The recommendations can be made in three areas of the dryer.

1. The cooling time of the bags after drying must be increased so as to prevent the effect of quenching. Currently after cooling the bags are directly taken out to a room temperature of 250C from 450C which causes quenching and condensation of moisture in the bag and results in the formation of water droplets in the packing.

2. The inlet air must be made 100% dry by using a de- humidifier in the inlet of the dryer. The cooling coil temperature of the de-humidifier must be the dew point of water, which assures the removal of water and other dust particles from the inlet air.

3. A filter of high grade must be used for the purification of inlet air, to avoid the entry of microbes through air.

4. In the arrangement of bags in trays inside the chamber is found to be thick and highly dense which will not provide complete circulation of hot air inside the chamber. So the arrangement of the bags must be made in spacious manner which makes sure the proper movement of hot air.

5. Currently the movement of hot air is in up-down motion as the inlet of air is in the bottom of the chamber and the blower is on the top of the chamber. By providing heating coils os blowers in the side walls of the chamber will accelerate the horizontal movement of air inside the chamber. By this the proper hot air circulation can be maintained.

CONCLUSIONS:
The main objective of study was to identify the major causes for the moisture accumulation in the primary packing of blood bags. Root cause analysis was conducted for the major causes for the moisture accumulation in the primary packing of blood bags. Root causes were identified using cause and effect diagram. Counter measures to prevent the major causes for the moisture accumulation in the primary packing of blood bags were also suggested.

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